

**A SAFETY AND FEASIBILITY STUDY OF ACTIVE IMMUNOTHERAPY IN
PATIENTS WITH METASTATIC PROSTATE CARCINOMA USING AUTOLOGOUS
DENDRITIC CELLS PULSED WITH RNA ENCODING PROSTATE SPECIFIC
ANTIGEN, PSA.**

NON-TECHNICAL ABSTRACT

The purpose of this research is to develop a new and powerful type of immune therapy for prostate cancer patients. This therapy involves vaccinations with special stimulator cells found in the human body called dendritic cells. These dendritic cells can take up proteins released from cancer cells and present pieces of these proteins to immune cells called T lymphocytes to create a strong stimulatory signal to fight the cancer.

One of these proteins is called prostate specific antigen (PSA) and is found on prostate cancers. However, in most cancer patients, though, the immune system does not adequately destroy the tumor because the T cells are not stimulated sufficiently. T cells require strong stimulation before they grow and become active against tumor cells.

We have discovered that substances called ribonucleic acids (RNA), which carry the genetic instructions for the production of PSA, can be used to overcome this problem and stimulate a strong immune response in cancer patients.

In order to test this hypothesis we have designed this study and will enroll patients with metastatic prostate cancer expressing PSA in order to determine whether or not this vaccine will stimulate T cells, which can recognize and kill PSA expressing prostate tumor cells.

The main objectives of this study are to find out whether injections with dendritic cells grown from blood cells and "pulsed" (mixed together for a short period of time) with RNA derived from the patient's own tumor are:

- a) safe without inducing any major side effects.
- b) and effective in boosting the patients body's immunity against PSA expressing prostate cancer cells.
- c) Finally we will test whether or not tumor shrinkage based on serum PSA levels or on X-ray studies will occur.

We hope that this new form of immune therapy, although in its infancy, will ultimately slow down tumor growth and prolong survival of prostate cancer patients.